



Amendment under 37 C.F.R. §1.111

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Lee et al.

Serial No.: 09/802,709

Filed: March 08, 2001

Title: METHODS AND DEVICES FOR PROVIDING PROLONGED DRUG THERAPY

### Extension of Time

A petition for a three-month extension of time and the fee therefore accompanies this response.

### The Rejection Under 35 U.S.C. §103(a)

Claims 1-34 were rejected under 35 U.S.C. §103(a), as obvious over Dong et al. (U.S. Patent No. 5,770,227) and Patrick et al., Biopharmaceuticals & Drug Disposition, 10:165-171 (1989). To the extent the rejection may apply to claims 2 and 58-68, it is respectfully traversed.

Dong et al. relate to a therapeutic composition of progesterone for hormone replacement therapy (column 1, lines 10-16). Dong et al. employ two different tablet cores that are combined to prepare a dosage form for dispensing progesterone to the gastrointestinal tract of a human, (see for example, Example 7 of the specification). The dosage form may further contain an interior surface facing the dual core design and an exterior surface coated on its exterior surface having a semipermeable wall (Example 11). The dosage form may also contain an osmagent (Example 15).

Patrick et al. merely provide a perspective on the absorption of sustained-release methylphenidate formulations compared to immediate release formulations (page 165). This perspective is provided by comparing 3 products: a 10 mg tablet of MPH-IR Ritalin®, a 20 mg tablet of MPH-SR Ritalin®, and a newly formulated 20 mg tablet of MPH-SR from MD Pharmaceuticals (Santa Ana, Ca) (page 166). The authors concluded that the three formulations demonstrated were equivalent in the extent of absorption (page 170).

Applicants respectfully traverse this rejection for a number of reasons. Establishment of a *prima facie* case of obviousness requires that the cited documents teach or suggest all of the limitations of the rejected claims. In addition, some suggestion or motivation must be provided to modify the documents to reach the claimed invention. Further, a document must be

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considered as a whole, including those portions of the document that teach away from the claimed invention.

Applicants respectfully submit that all of elements recited in claims 2 and 58-68 are not taught or suggested by Dong et al. and Patrick et al. Moreover, Applicants further submit that one of skill in the art would not be motivated to prepare a dosage form or methods as recited in Applicants' claims.

Dong et al. fail to teach or suggest any dosage form containing a single tablet core coated with a semipermeable membrane. Instead, Dong et al. employ two different tablet cores and combine these cores in a gelatin capsule. Moreover, Dong et al. is unrelated to a method for lessening the incidence of tolerance to methylphenidate to a patient or a method for treating attention deficient disorder in a patient .

Additionally, Dong et al. do not teach or suggest a dosage form that releases drug at a sustained and "increasing" dose as claimed by Applicants. Dong et al. merely provide an "acceptable oral means for administering progesterone at a controlled does over time," (column 1, lines 46-48). Moreover, Dong et al. fail to teach or suggest any dosage form having a single body core. Dong et al. relate only to combining two different tablet cores to prepare a dosage form. And, as pointed out by the Examiner, Dong et al. fail to teach or suggest a CNS acting drug, such as methylphenidate.

The secondary reference, Patrick et al., fails to supply that which is missing from Dong et al. Specifically, Patrick et al. merely provide a perspective on the absorption of sustained-release methylphenidate formulations compared to immediate release formulations. No teaching, suggestion or motivation is provided for the dosage forms and methods as claimed by Applicants.

For the above reasons, Applicants respectfully submit that the invention recited in claims 2 and 58-68 are patentable over Dong et al. in view of Patrick et al. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a) are respectfully requested.

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Conclusion

In light of the remarks presented herein, it is respectfully submitted that pending claims 2 and 58-68 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representative at the below-listed telephone number if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted,  
LAM et al.,  
By his Representatives,  
ALZA Corporation  
1900 Charleston Road  
Mountain View, CA 94043  
(650) 564-5000

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Date

PBS/KMG

By: Paul B. Simbol  
Paul B. Simbol  
Reg. No. 38,616  
Attorney for Applicants  
Direct Dial: (650) 564-7840